DEC 1 0 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

K011683

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Nuvo 9000 Endocavitary Coils
3. Classification :	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Nuvo 9000 Endocavitary Coils are three separate receive-only coils used to obtain diagnostic images of the anus, prostate, and cervix. The coils are designed to be inserted into either the rectum or vagina before imaging. The coils are delivered in a sterile state and are disposable, single-use devices. The indications for use are the same as for standard MR Imaging. The Nuvo 9000 Endocavitary Coils are designed for use with MRI Scanners manufactured by Marconi Medical Systems, Inc. and GE Medical Systems, Inc.
8. Device Description:	The Nuvo 9000 Endocavitary Coils are three separate disposable, receive-only MRI coils. The three separate coils are the prostate probe, the cervical probe, and the anal probe. The Nuvo 9000 Endocavitary Coils provide significant improvement in signal-to-noise ratios (SNR) and image resolution. The coils are designed to be inserted into either the rectum or vagina for imaging and can be used in conjunction with the USA Instruments' Insight Plus 9000 Torso and Pelvis Coil. The shape and dimensions of the three coils are similar to ultrasound probes used in endocavitary applications. The coils are housed in a rigid plastic housing and are connected to an interface box via a cable. An external immobilization device is also provided with the coils to stabilize the coil and limit motion. The physical structure of the coils, and use of an immobilization device, increases patient comfort and ease of positioning.

9. Safety and Effectiveness

Nuvo 9000 Endocavitary Coil Product Features	Comparison to predicate device or other 510(k) cleared product
Intended Use: Imaging the anus or prostate by insertion into the rectum, and the cervix by insertion into the vagina	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410) -Similar to the Philips Endocavitary MRI Coils manufactured by Philips Medical Systems, Inc. (K930193)
Indications for Use Identical to routine MRI imaging	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410) -Similar to the Philips Endocavitary MRI Coils manufactured by Philips Medical Systems, Inc. (K930193)
Coil Material GE Cycolac ABS Sylvan Technologies PVC	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410)
Coil Design Receive-only design	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410) -Similar to the Philips Endocavitary MRI Coils manufactured by Philips Medical Systems, Inc. (K930193)
Decoupling RF Chokes with Switching Diodes	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410)
Prevention of RF Burns Does not transmit RF Power, Decoupling isolates the coil elements from RF fields during RF transmission, Coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410) -Similar to the Philips Endocavitary MRI Coils manufactured by Philips Medical Systems, Inc. (K930193)
Radio Frequency Absorption Coil is a receive only coil and does not transmit RF power	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410) -Similar to the Philips Endocavitary MRI Coils manufactured by Philips Medical Systems, Inc. (K930193)
Formation of Resonant Loops Decoupling isolates coil elements from RF fields during RF transmission, Length of cable and stiffness does not allow permit looping	-Similar to the Hammersmith Endocavitary Coils manufactured by Marconi Medical Systems, Inc. (K981410)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2001

Mr. Rony Thomas
Vice President, Marketing
and Programs
USA Instruments, Inc.
1515 Danner Drive
AURORA OHIO 44202

Re: K011683
Trade/Device Name: Nuvo 9000 Endocavitary Coils
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: September 17, 2001
Received: September 17, 2001

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011683

Device Name: Nuvo 9000 Endocavitary Coils (Anal, Prostate, and Cervix)

Indications for Use: The Nuvo 9000 Endocavitary Coils are three receive only RF Coils designed to provide diagnostic images of the anus, prostate and cervix in Magnetic Resonance Imaging. The Nuvo 9000 Endocavitary Coils are single-use disposable devices that are delivered and packaged in a sterile state. The Nuvo 9000 Endocavitary Coils are designed for use with Marconi Medical Systems and GE Medical Systems MRI Scanners.

Anatomic Regions: Anus, Prostate, and Cervix
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The Marconi MRI Scanners and GE MRI Scanners are indicated for use as NMR devices that produce images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011683